B

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,692	10/14/2003	J. Milton Harris	044646/263188	3420

826 7590 09/06/2006

ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/684,692	**Applicant(s)** HARRIS ET AL.
	Examiner David M. Naff	**Art Unit** 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date *6/14/06*.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

An amendment of 6/14/06 in response to an office action of 3/14/06 amended claims 1, 3 and 4.

Claims examined on the merits are 1-4, which are all claims in the application.

Document 19 on form 1449 of 6/14/06 has been lined through since the document was previously listed on the 1449 of 8/19/04.

The double patenting rejection is withdrawn in view of the terminal disclaimer accompanying the amendment.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are unclear how "heterobifunctional" in line 1 of claim 1 limits the formula recited. According to the specification (page 8, paragraph 0034), heterobifunctional means one termini is acrylate and the other is a target molecule or a functional group capable of coupling the polymer to a target. However, acrylate is capable of coupling a target or coupling to a polymer. Therefore, the definition of heterofunctional in the specification encompasses both termini being acrylate. Claim 1 should be amended to require Q to be selected from a group as required by claim 4, and delete claim 4.

Claim Rejections - 35 USC § 103

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoyama et al (5,977,277) in view of Yang et al (Document 18 on 1449), and if necessary in further view of Greenwald et al (5,840,900)

The claims are drawn to a heterobifunctional compound represented by the formula: $CH_2=CZ-CO_2-POLY-W-POLY'-Q$ where z represents H or alkyl; POLY and Poly' represent a poly(alkylene oxide) of formula $-(CH_2CHRO)_n-CH_2CHR-$ in which R is H or alkyl, and n is 10-100; Q represents a functional group; and W represents a hydrolytically unstable linkage.

Yokoyama et al disclose a poly(alkylene oxide) acrylate compound II (col 2, lines 40-51) having a formula within the scope of the claimed formula except that the compound contains acrylate at both termini so as to be homofunctional instead of heterofunctional as presently claimed.

Yang et al disclose a heterobifunctional poly(ethylene glycol) acrylate having an acrylate group on one terminus and an active ester at the other terminus. For example, see Fig. 10 (page 4849). The active ester terminus reacts with an enzyme and the acrylate terminus participates in polymerization to immobilize the enzyme (page 4843, paragraph bridging the columns and page 4849 under "Conclusions").

Greenwald et al disclose a prodrug composition containing a hydrolyzable linkage such as an ester linkage between a polymer portion and a biologically active moiety for release of the biologically active moiety (paragraph bridging cols 4 and 5). The polymer may be PEG-acid or PEG-diacid having the hydrolyzable linkage (col 7, lines 1-15 and col 12, lines 20-61).

It would have been obvious make the compound of Yokoyama et al heterobifunctional by replacing the acrylate of one terminus with an active ester so different termini can participate in different reactions as suggested by Yang et al providing a heterobifunctional compound having an active ester termini for reacting with an enzyme and an acrylate termini for reacting to form a polymer. The $-CO_2-$ between the first and second (CH_2CH_2O) of the formula of Yokoyama et al is a hydrolytically unstable linkage. If not, it would have been obvious to provide such a linkage as suggested by Greenwald et al using PEG containing a hydrolyzable linkage for release of a biologically active moiety. The polyethylene glycol of claim 2 is suggested by Yang et al. The $-CO_2-$ of the formula of Yokoyama et al is a carboxylate ester as encompassed by claim 3. It would have been obvious from Yang et al, and if needed Greenwald et al, to use a group as required by claim 4 as the terminus other than acrylate.

Response to Arguments

The response urges that the compound of Yokoyama et al is homobifunctional rather than heterobifunctional. However, for reasons set froth above, in view of Yang et al disclosing a heterobifunctional compound having an acrylate termini with another group as the other termini, making the compound of Yokoyama et al heterobifunctional would have been obvious.

The response urges that Yokoyama et al is directed to a different field of using polymer systems as liquid electrolytes in an electrochemical element. However, Yokoyama et al disclose (col 6, lines 53-57) that the terms polymerization and polymer are not limited to homopolymerization and a homopolymer, but comprehend copolymerization and a copolymer. A heterobifunctional compound would have been obvious to produce a copolymer since two different termini can react with two different monomers. The presently claimed compound can be used as a compound to produce the copolymer of Yokoyama et al. While Yokoyama et al and Yang et al are in different fields as urged by the response, both are drawn to bifunctional poly(ethylene glycol) acrylates, and it would have been obvious to look at all fields where such acrylates are used.

The response urges that Yang et al do not want the polymer to break down. However, the hydrolytically unstable linkage of the present claims will not result in a break down unless the polymer is subjected to hydrolytic conditions capable of hydrolyzing the linkage. Therefore, the hydrolytically unstable linkage can be present, and break down not occur until suitable hydrolysis conditions are present. In any event, the compound of Yokoyama et al contains a linkage that the present claims encompass as hydrolytically unstable.

The response urges that the linkage of Greenwald et al hydrolyzes *in vivo*. However, the linkage of the present claims can hydrolyze *in vivo* if conditions suitable for hydrolysis are present.

Bentley et al and Loomis et al are made of record to further show compounds related to those presently claimed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David M. Naff
Primary Examiner
Art Unit 1651

DMN
9/1/06